

### **DETAILED ACTION**

This Office Action is written in response to Applicants Remarks filed 1/31/11. Claims 47-85, 90, 93, 94, 97-105 are withdrawn from consideration. Claims 86-89, 91, 92, 95, 96, 106-111 have been examined. Claims 106-111 are new.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86-89, 91, 92, 95, 96, 106-111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 86 has been amended to recite: a) providing a solution of one or more globular proteins, in which solution the protein is at least partially denatured and at least partially aggregated in fibrils; and b) performing one or more of the following steps in random order:

- i) adjusting the pH of the solution to about neutral;
- ii) increasing the salt concentration in the solution;
- iii) concentrating the solution;
- iv) changing the solvent quality of the solution.

There is no support for the recitation "in which solution the protein is at least partially denatured and at least partially aggregated". There is no support for the simultaneous partial denaturation and partial aggregation. Applicants point to page 4, lines 1-29, claim 47, 48, 58 of the specification.

Nowhere in this portion of the specification is there a disclosure of both partial denaturation and

partial aggregation. Examiner agrees that the support is found for partial aggregation. Examiner does not agree that support is found for the term "partial denaturation" or also partial denaturation coupled with partial aggregation.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 86-89,91, 92, 95, 96, 106-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 86, the phrase "performing one or more of the following steps in random order" is indefinite because it is unclear whether the "one or more" limitation is referring to the fact that all of the steps are required for the claim or whether all of the steps are required but can be performed in any order.

5. Regarding claim 86, the phrase "about neutral" renders the claims indefinite because the claims include elements not actually disclosed (those encompassed by "about neural"), thereby rendering the scope of the claims unascertainable. See MPEP § 2173.05(d).

#### *Claim Rejections - 35 USC § 103*

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 86, 87, 88, 91, 92, 95, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernardin (US 3,993,794).**

**Regarding Claims 86, 87, 92 and 96:** Bernardin discloses proteins aggregated to produce microfibrils, that the microfibrillated protein has gel forming properties and that the microfibrillated protein is used in the preparation of meat products [col. 1, lines 46-61; col. 2, lines 9-22]. Although

Bernardin does not disclose improved functional properties as compared with proteins that are not aggregated to produce fibrils, it would have been obvious to one of ordinary skill in the art that since Bernardin discloses the protein fibers have enhanced bite, texture and appearance that allows it to be used in meat products and that the fibers imitate the texture of meat, that the protein having a fibril texture would have had improved properties in the application of certain foods versus proteins that did not have the fibril texture.

Bernardin does not disclose that the microfibrillated protein is formed by:

- a) providing a solution of one or more globular proteins, in which solution the protein is at least partially denatured and at least partially aggregated in fibrils; and
- b) performing one or more of the following steps in random order:
  - i) adjusting the pH of the solution to about neutral;
  - ii) increasing the salt concentration in the solution;
  - iii) concentrating the solution;
  - iv) changing the solvent quality of the solution.

However, regarding the process steps of the claim, since there is no evidence that the recited process produces a product that is materially different from what is disclosed in the prior art, claim 86 has been considered regarding its disclosure of proteins at least partially aggregated in fibrils wherein the protein additive has improved functional properties as compared with similar proteins that are not aggregated to produce fibrils. “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior art was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698.

**Regarding Claim 88:** Bernardin discloses proteins aggregated to produce microfibrils as discussed above. Since there is no evidence that the recited process produces a product that is materially different from what is disclosed in the prior art, claim 88 has been considered regarding its disclosure of protein in microfibril form.

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698.

**Regarding Claims 91 and 95:** Bernardin discloses proteins aggregated to produce microfibrils as discussed above but does not explicitly disclose the protein used in dairy products. However, it would have been obvious to one of ordinary skill in the art to incorporate the protein of Bernardin in dairy products since Bernardin discloses the incorporation of its protein in puddings, gelled desserts, and dressings and because these products have textures or consistencies that are similar to dairy products such as yogurt, cottage cheese, and other milk products etc.

8. **Claims 86, 87, 88, 91, 92, 95, 96, and 106-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altemueller et al. (US 6,355,295) in view of Sakata et al. (US 2003/0013852).**

**Regarding Claim 86:** Altemueller discloses a soy material food ingredient (protein additive) that contains partially denatured soy protein that form aggregates where the denatured proteins align with each other to reduce the exposure of the hydrophobic portions to the solution

[col. 11, lines 33-52]. Altemueller discloses that the soy material has functional properties similar to soybean concentrate that has gone through extensive processing [col. 3, lines 47-56]. Although Altemueller does not explicitly disclose fibrils, Altemueller does disclose that the denatured proteins align with each other, and this is indicative of the fibrillar structure of the protein.

Altemueller discloses that soy protein in its native state is globular and that following the method of making soy material, the soy protein is denatured and aggregated [col. 11, lines 36-38].

Altemueller discloses concentrating and changing the solvent quality of the soybean protein solution by removing water, pentane, hexanal etc which are solvents, by flash vaporization and spray drying [col. 23, lines 56-67, col. 24, lines 1-16]. Altemueller does not disclose adjusting the pH of the solution to about neutral; and increasing the salt concentration in the solution.

Sakata discloses denaturing soybean protein slurry and after ward neutralizing the soybean protein slurry to a pH of 6 to 8 or 6.5 to 7.5 [0022, 0023]. Sakata also discloses adding salt of an organic acid to the solution upon neutralizing the soybean protein slurry [0022, 0023]. Sakata discloses that neutralizing the solution is necessary after denaturing the protein in order to prevent sour taste formation [0021].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Altemueller and Sakata before him or her to modify the method of Altemueller to include a step of neutralizing the soy protein after denaturing in order to prevent sour taste formation especially since a sour taste originating from soy could render the soy protein undesirable for inclusion in certain food products.

**Regarding Claim 87:** Altemueller discloses that the soy material has thickening and gelling properties, and helps to form a firm texture in emulsions [col. 11, lines 50-52; col. 12, lines 48-67; col. 26, lines 55-58].

**Regarding Claim 88:** Altemueller discloses proteins aggregated as discussed above. Since there is no evidence that the recited process produces a product that is materially different from what is disclosed in the prior art, claim 88 has been considered regarding its disclosure of protein additive.

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698.

**Regarding Claim 89:** Altemueller discloses that the soy material is in dry form [col. 13, lines 62-67; col. 14, lines 64-67; col. 15, lines 1-7].

**Regarding Claims 91 and 95:** Altemueller discloses that the soy material is used in dairy products [col. 26, lines 55-61]. Altemueller does not give explicit examples of a dairy product containing the soy material (claim 95). However, Altemueller explicitly discloses that the soy material is useful in yogurts and dairy products, therefore it would have been obvious to one of ordinary skill in the art to provide a dairy product containing the soy material.

**Regarding Claims 92 and 96:** Altemueller discloses that the soy material is used in meat products [col. 26, lines 51-67; col. 27].

**Regarding Claims 106, 109, and 110:** Altemueller discloses soy material in its native state and that in its native state soy protein is globular, as discussed above. Altemueller discloses that the soy is denatured by heating at 75°C to 160°C. Altemueller does not disclose that the soy is denatured at a pH between 0.5 and 4; 0.4 to 2.8 (claim 109); and 0.4 to 2.2 (claim 110).

Sakata discloses treating soy protein under acidic conditions for the purpose of reducing intense soybean odor. Sakata discloses treating at a pH of 2.0 to 4.0 [0013].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Altemueller and Sakata before him or her to modify the process of Altemueller to include the step of an acidic treatment in order to reduce the soybean odor in the soybean protein. The adverse effect of the presence of soybean odor is that it negatively alters the flavor naturally associated with food when the soybean protein is used with the food product [Sakata 0005].

Although Altemueller does not disclose the heating temperature at 50°C to 100°C, since Altemueller discloses a range of 75°C to 160°C one having ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Altemueller overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. *In re Malagari* 182 USPQ 549,553.

Although Sakata does not explicitly disclose the pH ranges as 0.5 to 4, and 0.4 to 2.8, and 0.4 to 2.2 since Sakata discloses a pH range of 2.0 to 4.0, one having ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Sakata overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. *In re Malagari* 182 USPQ 549,553.

**Regarding Claim 107:** Altemueller discloses heat treating for a period of 2 seconds to about 2 hours [col. 23, lines 5-10].

Although Altemueller does not disclose at least 1 hour one having ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because

the compositional proportions taught by Altemueller overlap the instantly claimed proportions and therefore are considered to establish a *prima facie* case of obviousness. *In re Malagari* 182 USPQ 549,553.

**Regarding Claim 108:** Altemueller discloses heat treating for a period of 2 seconds to about 2 hours [col. 23, lines 5-10]. Further Altemueller discloses that the time for exposure is temperature dependent [col. 23, lines 9-13].

Although Altemueller does not disclose at least 8 hours, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the time for exposing the protein to heat in order to achieve the desirable level of denaturation of the protein for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

9. **Claim 111 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altemueller et al. (US 6,355,295) and Sakata et al. (US 2003/0013852) as applied to claim 106 above and in further view of Yokotsuka et al. (US 3,897,570).**

**Regarding Claim 111:** Altemueller discloses denaturing soy material as discussed above. Altemueller does not disclose denaturing with ureum, guanidinium chloride and alcohols, such as methanol, ethanol, propanol, butanol and trifluorethanol.

Yokotsuka discloses the preparation of soybean material by denaturing soy material with ethanol or other lower alcohol not only to denature the protein but also to remove odorous components and coloring from soy [col. 4, lines 14-33].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Altemueller, Sakata, and Yokotsuka before him or her to modify the process

of Altemueller to include the step of denaturing with an alcohol such as ethanol in order to reduce the odor in and the color of the soybean protein in addition to changing the original structure of the soy protein.

***Response to Arguments***

10. Applicant's arguments with respect to the amendments made to claims 86, 87, 88, 91, 92, 95, 96, and new claims 106-110 have been considered but are moot in view of the new grounds of rejections made in the above Office Action.

***Conclusion***

11. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FELICIA C. KING whose telephone number is (571)270-3733. The examiner can normally be reached on Mon- Thu 7:30 a.m.- 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m. alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Humera Sheikh can be reached on 571-272-0604. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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